Remarks/Arguments:

Prior to the amendments set forth in this response, the claims pending in this application are 54-121.

Claims 85-92 were presented in a Fourth Preliminary Amendment that was filed on October 15, 2004, three days before the mailing date of the present Office Action. Claims 93-121 were presented in a Fifth Preliminary Amendment that was filed on February 2, 2005. As noted in the Remarks to the Fifth Preliminary Amendment, that document was captioned as a Preliminary Amendment based on the Examiner's statement that the USPTO would withdraw the October 18, 2004 Office Action and issue a Supplemental Office Action, which statement was consistent with the statement made by the Examiner's Supervisor to applicants' representative on December 20, 2004.

During a telephone interview between applicants' undersigned representatives on February 28 and March 4, 2005, the Examiner confirmed that the Fourth and Fifth Preliminary Amendments had been entered but stated that a Supplemental Office Action would not be issued. Accordingly, as of the filing of this response to the Office Action dated October 18, 2004, the claims pending in this application are 54-121.

Because claims 85-92 are believed to be identical to claims 54-61, claims 85-92 are now canceled without prejudice or disclaimer of the subject matter therein. Claim 122 has been added. No new matter is introduced therein. With the amendments set forth in this response, the pending claims are 54-84 and 93-122.

I. Rejection Of Claims 57-59, 61-63 Under 35 U.S.C. § 112, First Paragraph

On page 2, paragraph 4 of the Office Action, claims 57-59 and 61-63 have been rejected under 35 U.S.C. § 112, first paragraph. The Office Action contends that the recitation "markers disposed on at least one of the frame, the liner, and the attachment mechanism" is not described in the specification. The Office Action also contends that the phrase "rotational indicator" is not described in the specification.

A. Markers

The specification at least describes "markers disposed on. . .the frame." For example, the Examiner's attention is directed to the following passage:

> An x-ray opaque marker may be attached to one or more ends of a stent so that the delivery of the stent can be monitored using x-rays. As shown in Figure 4(a), such a radiopaque marker may typically comprise a gold or platinum wire 17 crimped onto an end of stent 16. Alternatively, the radiopaque marker may be a tube 17a disposed around a length of wire on the stent, also as shown in Figure 4(a). Typically, in the bifurcated stent the marker is secured to the stent in line with the distal stent portion so that the distal stent portion can be aligned with and inserted into one of the branched arteries in situ. (page 28, lines 1-12).

In view of the foregoing passage, for example, the specification clearly supports markers disposed on the frame. The Examiner is also invited to consider new claim 122, which recites markers disposed on the frame.

B. Rotational Indicator

The phrase "a rotational indicator" is recited in claim 59. The specification supports this recitation as in the following example:

> While maintaining proximal portion pusher 102 in a fixed position, outer sheath 101 is withdrawn until the proximal end of the prosthesis emerges from outer sheath 101 as shown in Fig. 13. Using a radiopaque marker 120 disposed on proximal end of the prosthesis, the introducer is rotated until proper alignment of the prosthesis is obtained. In the illustrated embodiment, radiopaque marker 120 is a platinum wire twisted around an apex of the prosthesis in a "V" shape. To ensure proper alignment, the stent should be rotated until only the profile of the V is seen and shows up as a straight line rather than a "V". (page 39, lines 12-23)

At least this portion of the specification therefore provides support for the phrase "rotational indicator" in claim 59.

Although page 2, paragraph 4 of the Office Action also rejected claims 61-63, claims 61-63 do not contain the phrase "markers disposed on at least one of the frame, the liner, and the attachment mechanism" or the phrase "a rotational indicator." Applicants believe that the rejection of claims 61-63 has been explained in paragraph 5 on page 2 of the Office Action. Accordingly, applicants have responded to the rejection of those claims below.

II. Rejection Of Claims 61-63 Under 35 U.S.C. § 112, First Paragraph

On page 2, paragraph 5 of the Office Action, claims 61-63 have been rejected under 35 U.S.C. § 112, first paragraph. The Office Action contends that the specification fails to disclose three features.

A. The First Feature

The first feature mentioned by the Office Action is:

> The step of aligning an image of markings disposed on at least one of the first prosthetic module and the second prosthetic module with an image of the other of the first prosthetic module and the second prosthetic module.

This feature is recited in claim 61. The feature is supported at least by the following part of the specification, for example:

> Distal portion 44 is pushed through outer sheath 301, which remains in a fixed position, until distal portion 44 is at proximal end 320 of outer sheath 301 (see Figure 19). Again, radiopaque markers 120 may be used to align distal portion 44 properly with proximal portion 12. (page 43, lines 13-18).

As shown in Figure 13, for example, radiopaque markers 120 are disposed on the proximal end of the prosthesis (see, page 39, lines 15-16). Radiopaque markers are used "so that the delivery of the stent can be monitored using x-rays" (page 28, lines 2-3). Because claim 61 is

supported by the specification, applicants request that this rejection of claims 61-63 be withdrawn.

B. The Second Feature

The second feature mentioned by the Office Action is:

> A different radiopacity of a portion for facilitating proper alignment of first and modules [sic] with respect to one another during an engagement.

This feature, as recited by the Office Action, is not found in the claims. The closest recitation is found in claim 62, which recites:

> a portion of at least one of said modules has a different radiopacity, said portion of different radiopacity facilitating proper alignment of said modules with respect to one another during said engagement.

This feature does find support in the specification. Figure 4(a), for example, shows a radiopaque marker crimped or otherwise disposed onto an end of stent 16 (page 28, lines 1-12). Markers such as markers 17 (Figure 4(a)) and 120 (Figure 13) are used to align modules (page 28, lines 8-12; page 43, lines 16-18). When a radiopaque marker is placed onto a stent, that portion of the stent has a different radiopacity than the other parts of the stent. The differences in radiopacity allow the user to align the modules. Accordingly, this feature of claim 62 is supported by the specification and applicants request that this rejection be withdrawn.

C. The Third Feature

The third feature mentioned by the Office Action is:

> A composite radiographic image of said radiographic indicia varies with the rotational orientation of a module.

Figure 4(a), for example, shows a radiopaque marker 17 in a "V" shape. As noted above, a stent with a "V" shaped marker is "rotated until only the profile of the V is seen and shows up as a straight line rather than a "V" (page 39, lines 21-23). The result of this rotation is that "the composite radiographic image of said radiographic indicia varies with the rotational orientation of said module" as recited in claim 63. Accordingly, this feature of claim 63 is supported by the specification and applicants request that this rejection be withdrawn.

III. The Double Patenting Rejection

Claims 60 and 61 have been rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claim 1 of U.S. Patent No. 5,609,627. A terminal disclaimer will be filed in due course.

IV. Rejections Under 35 U.S.C. § 102(e)

Claims 54, 55, 57-65, 67-70 and 84 have been rejected under 35 U.S.C. § 102(e) as anticipated by Chuter (U.S. Patent No. 5,387,235).

In the Second Preliminary Amendment, claims 67-69 were substantially copied from claims 1, 10, and 20, respectively, of U.S. Patent No. 6,582,458 issued to White et al. In the Third Preliminary Amendment, claims 70 and 84 were substantially copied from claims 1 and 19, respectively, of U.S. Patent No. 6,613,073 issued to White et al. The October 21, 1992 filing date of Chuter is earlier than the White '458 priority date and the White '073 priority date.

Based on the foregoing, the MPEP requires the approval of the TC Director before claims 67-70 and 84 may be rejected over Chuter. Specifically, MPEP 2307.02 states:

> The ground of rejection of the claims presented may or may not be one which would also be applicable to the corresponding claims in the patent. If the ground of rejection is also applicable to the corresponding claims in the patent, any letter including the rejection must have the approval of the TC Director. See MPEP § 1003.

MPEP § 1003 states, in part:

> The following is a list of matters which are submitted to the appropriate Technology Center Director, together with a reference to any section of this manual where such matters are more fully treated.
>
> * * * * * * * *
>
> 6. Actions which hold unpatentable claims copied from a patent for interference purposes where the grounds relied upon are equally applicable to the patentee, MPEP § 2307.02.

For these reasons, applicants request that the rejection of claims 67-70 and 84 as anticipated by Chuter be withdrawn unless the rejection is approved by the TC Director.

Claim 54 recites, in part:

> a plurality of radially expandable prosthetic modules, each module having a tubular body portion and an end which fittingly engages at least one of the common lumen, the first branch lumen, and the second branch lumen;
>
> wherein the plurality of body portions provide different selectable assembled endoluminal prosthetic characteristics.

The Office Action contends that Chuter discloses a Y-connector module 206 and branch modules 246 and 247. Chuter does not disclose a plurality of modules. Chuter discloses a graft 206 having limbs 210, 213 and extensions 246 and 247 that are sutured to limbs 210 and 213 (col. 19, lines 16-24). There is no disclosure in Chuter that it has "different selectable assembled endoluminal prosthetic characteristics" or that its graft limbs "fittingly engage[]" limbs 210 or 213.

Accordingly, claim 54 is not subject to rejection under 35 U.S.C. § 102(e) as anticipated by Chuter. Because claim 55 depends from claim 54, it is not subject to the same rejection at least for the same reasons that claim 54 is not subject to rejection.

Amended claim 57 recites, in part:

> markers disposed on at least the frame, the markers visible under imaging to indicate at least one of axial and rotation position of the stent-graft.

The Office Action contends that column 17, lines 40-52 of Chuter discloses these features. Applicants disagree. Although Chuter does disclose markers 211 and 212 on graft limb 210 (col. 17, lines 41-52; col. 25, lines 51-52), the markers are used to reveal twisting of contralateral limb 210. Chuter does not disclose that the markers are used "to indicate at least one of axial and rotational position of the stent-graft" as recited in claim 57. Accordingly, claim 57 is not subject to rejection under 35 U.S.C. § 102(e) as anticipated by Chuter. Since claims 58 and 59 depend from claim 57, they are not subject to the same rejection for at least the same reasons.

Claim 60 recites, in part:

> selecting a preferred first branch prosthetic module from a plurality of alternative branch prosthetic modules having differing prosthetic characteristics; and
>
> positioning an end of the preferred first branch prosthetic module within the first branch of the body lumen and radially expanding the preferred first branch prosthetic module, the expanded preferred first branch prosthetic module engaging the Y-connector prosthetic module.

Chuter does not disclose the steps recited above. There is no disclosure in Chuter that limbs 213 and 246, for example, are sutured together or otherwise positioned after the step of "inserting a Y-connector prosthesis module within a body lumen." Accordingly, claim 60 is not subject to rejection under 35 U.S.C. § 102(e) as anticipated by Chuter.

Claim 61 recites, in part:

> aligning an image of markings disposed on at least the second prosthetic module with an image of the first prosthetic module and the second prosthetic module; and
>
> expanding an end of the aligned second prosthetic module to engage an end of the first prosthetic module.

The Office Action has not identified where Chuter discloses these features, and it is respectfully submitted that claim 61 is not subject to rejection under 35 U.S.C. § 102(e) as anticipated by Chuter.

Claims 62-65 depend from claim 54. Consequently, these claims are not subject to rejection for at least the same reasons that claim 54 is not subject to rejection.

Claim 67 recites, in part:

> a graft which is adapted to be anchored within one of the flow lumens of said bifurcated base structure to form a continuous extension of that lumen.

The Office Action contends that the term "adapted" "does not impose any structure limitation on the claims distinguishable over the Chuter's device that is capable of being used as claimed if one desires to do so." Applicants respectfully disagree. All of the words of a claim must be given weight. Chuter does not disclose a graft that is capable of being "anchored within one of the flow lumens of said bifurcated base structure." Accordingly, claim 67 is not subject to rejection under 35 U.S.C. § 102(e) as anticipated by Chuter.

Claim 68 recites, in part:

> a second graft defining a lumen and adapted to be intravascularly inserted into a lumen of said first graft. . .; and
>
> wherein said first distal portion has a downstream end forming a skirt.

The Office Action has not pointed to anything in Chuter that discloses these features. In fact, Chuter does not disclose them. First, the term "adapted" must be given patentable weight. Second, the Office Action incorrectly contends that Chuter discloses that the first distal portion of the first graft "has a downstream end forming a skirt" 201. Element 201 is not part of a graft. Instead, element 201 is a segment of a stent. See Figure 21 (col. 16, lines 59-60). For all of the above reasons, claim 68 is not subject to rejection under 35 U.S.C. § 102(e) as anticipated by Chuter.

Since claim 69 depends from claim 67, it is not subject to rejection at least for the same reasons that claim 67 is not subject to rejection.

Claim 70 recites, in part:

> a supplemental graft body, . . .said first end of said supplemental graft body being dockable to said second portion of said primary graft body while inside of a vessel. . . .

The Office Action contends that the term "dockable" "does not impose any structure limitation on the claims distinguishable over the Chuter's device that is capable of being used as claimed if one desires to do so." Applicants disagree. Every term in a claim must be given weight. Even if the Office Action considers elements 246 and 247 to be supplemental graft bodies which is not clear from the Office Action and which applicants dispute), neither of them are dockable to limbs 210 and 213 "while inside of a vessel." The Office Action has not pointed to anything in Chuter that discloses this feature. Accordingly, claims 70 and 84 are not subject to rejection under 35 U.S.C. § 102(e) as anticipated by Chuter.

V. Rejections Under 35 U.S.C. § 103(a)

In paragraph 11 of the Office Action, claims 56 and 66 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Chuter in view of Venbrux (U.S. Patent No. 5,443,497).

Claim 56, which depends from claim 54, recites an endoluminal prosthesis system wherein

> engagement of the end of each prosthetic module with the Y-connector module affixes the prosthetic module and the Y-connector module with an axial overlap.

The Office Action acknowledges that Chuter does not disclose an overlap between a portion of the Y-connector and the branch modules. However, the Office contends that Venbrux discloses a graft being overlapped at a connecting area. Therefore, the Office Action contends, it would have been obvious "to provide an overlap between the connection of the branch modules and the Y-connector in order to better secure and provide a better flow path and minimize turbulence of fluid flowing there through." In other words, the Office Action appears to contend that it would have been obvious to fittingly engage tubular extensions 246, 247 to limbs 213, 210 with an axial overlap. Applicants disagree.

The type of prostheses disclosed in Chuter and in Venbrux are completely different and have completely different purposes. The purpose of the device in Chuter is the repair of aneurysms (col. 1, lines 15-16), with a devise inserted into the aorta at the site of the aneurysm (See, e.g., Figs. 14, 15; col. 12, lines 37-38). The purpose of the device in Venbrux, however, is to provide an arterial bypass (col. 1, lines 6-8). The bypass element 16 is outside, and bypasses, artery 42 of vessel 50. In Chuter, prosthesis 206 is Y-shaped and the extensions 246, 247 are sutured (not engagingly affixed, as recited in claim 54) to the ends of limbs 213, 210.

Furthermore, the purpose of tubular extensions 246, 247 is to provide "caudal limb control mechanisms" that "extend from caudal ends of limbs 210 and 213 of graft 206 to the level of the skin" (col. 19, lines 5-6). The ends of the limbs extend outside the body (col. 19, lines 11-14). In addition, the extensions 246, 247 are detachable (col. 19, lines 7-8). In contrast, bypass member 20 in Venbrux must stay inside the body so that it can convey blood flow from stent 12 to stent 14. If the teachings of Venbrux were applied to the Chuter device, the modified Chuter device could not function as it was designed to operate. Therefore, it would not have been obvious to combine the teachings of the two devices.

Consequently, claim 56 is not subject to rejection under 35 U.S.C. § 103(a) as unpatentable over Chuter in view of Venbrux.

Claim 66 depends from claim 54. It recites, in part:

> a male engaging portion on a selected one of said modules, and a female portion on another one of said modules, said male engaging portion being configured to be positioned at least partially within said female portion. . .
>
> said graft layer being configured to be interposed between said male engaging portion and said female portion to form a substantially fluid-tight seal upon assembly.

Applicants incorporate by reference their arguments regarding the rejection of claim 56. The Office Action does not point to anything in either reference which discloses or suggests "said graft layer being configured to be interposed between said male engaging portion and said female portion to form a substantially fluid-tight seal upon assembly." Accordingly, claim 66 is not subject to rejection under 35 U.S.C. § 103(a) as unpatentable over Chuter in view of Venbrux.

In paragraph 12 of the Office Action, claims 71-83 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Chuter. These claims depend from claim 70.

Claim 70 is not subject to rejection under 35 U.S.C. §102(e) as anticipated by Chuter. In addition, there is no suggestion in Chuter to modify the device disclosed in his patent to provide a supplemental graft body that is dockable to the primary graft body while inside a vessel. Because claims 71 and 75 depend from claim 70, claims 71 and 75 are not subject to rejection under 35 U.S.C. § 103(a) as unpatentable over Chuter.

Apparently referring to claims 71 and 75, paragraph 12 of the Office Action contends that "[i]t is well known in the art to provide a bifurcated graft with circumferential reinforcing members as claimed such as with a stent having a plurality of separate space apart wires." The USPTO may rely on "common knowledge" only in limited circumstances. MPEP 2144.03. "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, to be common knowledge in the art are capable of instant and unquestionable demonstration as being well known." MPEP 2144.03. "It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art." MPEP 2144.03. "It is never appropriate to rely solely on 'common knowledge' in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based." MPEP 2144.03. Applicants therefore request the PTO to provide authority and evidence in support of the rejection. Such evidence must be substantial evidence in support of its position. *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

For the above reasons, claims 71 and 75 are not subject to rejection under 35 U.S.C. §103 as unpatentable over Chuter. Claims 72-74, 79, 81 depend from claim 71. Claims 76-78, 80 depend from claim 75. Claims 82-84 depend from claim 70. Accordingly, these claims are not subject to rejection for at least the same reasons that claims 70, 71, and 75 are not subject to rejection.

VI. Conclusion

For the foregoing reasons, applicants respectfully submit that the pending rejections should be withdrawn. Accordingly, applicants request favorable reconsideration of claims 54-84 and 93-122.

Respectfully submitted,

Joshua L. Cohen

Joshua L. Cohen, Reg. No. 38,040
Stanley Weinberg, Reg. No. 25,276
Attorneys for Applicants

SW/pb

Dated: April 18, 2005

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: April 18, 2005

Joshua L. Cohen

Joshua L. Cohen

PCB_I:\BSI\210US7\AMEND01.DOC